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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/997,464	12/23/97	STERN D	54202/JPW/SB

HM22/0302

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EXAMINER	
KERR, J	

ART UNIT	PAPER NUMBER
1633	5

DATE MAILED: 03/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/997,464	Applicant(s) Stern et al.
	Examiner Janet M. Kerr	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Nov 12, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *0* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-33* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-33* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 11, and 12, drawn to a method for evaluating the ability of a compound to inhibit neurotoxicity, and a pharmaceutical composition containing a compound identified by the method, classified in class 435, subclasses 4, 7.1, 7.2, and 7.21, and class 424, subclasses 9.1 and 9.2, for example.

II. Claims 6-10, drawn to a method for evaluating the ability of a compound to inhibit binding of an amyloid-β peptide to a receptor, classified in class 435, subclasses 4, 7.1, 7.2, and 7.21.

III. Claims 11-20, drawn to a method of treating a neurodegeneration condition with a pharmaceutical composition, classified in class 424, subclasses 9.1 and 9.2, for example.

IV. Claims 21-30, drawn to a transgenic animal which expresses human presenilin-2 protein or a mutant human presenilin-2 protein and a human receptor for advanced glycation end product protein, and a diagnostic method using the transgenic animal, classified in class 800, subclasses 3, 8, 9, and 13, for example.

V. Claims 31-33, drawn to cells containing a recombinant nucleic acid comprising DNA encoding mutant presenilin-2 protein and encoding a receptor for advanced glycation end product protein , classified in class 435, subclasses 172.1, 172.3, 368, and 455, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, V and III-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I and II are drawn to *in vitro* diagnostic methods which do not require the inventions of group III, drawn to a treatment method, or the invention of group IV, drawn to non-human transgenic animals and methods of use, as the diagnostic methods of Inventions I and II can be performed *in vitro* with transformed cells, while

the method of Invention IV requires a non-human transgenic animal for reduction to practice.

Inventions I and II are distinct from Invention V in that the diagnostic methods of inventions I and II do not require the cells of group V, i.e., cells containing naturally occurring mutations in the human presenilin-2 protein can be utilized in the diagnostic methods. Moreover, the cells of group V can be used for purposes other than in the diagnostic methods of Inventions I and II, e.g., the cells can be used as a source of mutated human presenilin-2 protein for the purpose of generating antibodies.

Inventions I and II, drawn to diagnostic methods, are patentably distinct as the methods require different technical considerations, different reagents, and different mechanisms of action. For example, the method of Invention I requires a determination of cell death, a mechanism of action not required to reduce to practice the method of Invention II, which requires measurements of binding activities.

Invention III, drawn to a method for treating neurodegeneration is distinct from the inventions of groups IV and V as the method does not require the use of a transgenic animal or host cells containing recombinant nucleic acids.

Invention IV, drawn to transgenic animals and methods of use, is distinct from Invention V, drawn to cells containing recombinant nucleic acid in that the transgenic animals are used for *in vivo* diagnostics while the cells can be used for *in vitro* diagnostics.

The several inventions above have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to John P. White on 2/18/99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Brian Stanton, Supervisory Primary Examiner of Art Unit 1633, at (703) 308-2801. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401. Any inquiry of a general nature or relating to the status of this

application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633.

Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600
March 1, 1999

BRIAN R. STANTON
PRIMARY EXAMINER
GROUP 1600
1633